DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2015

Sonendo, Inc.
Ms. Jenny Fam
Senior Director of Regulatory Affairs
26061 Merit Circle, Suite 101
Laguna Hills, California 92653

Re: K143448
Trade/Device Name: Sonendo GentleWave™ System
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: March 30, 2015
Received: March 31, 2015

Dear Ms. Fam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K143448

Device Name: **Sonendo GentleWave System**

Indications for Use:

The Sonendo GentleWave™ System is intended to prepare, clean, and irrigate teeth indicated for root canal therapy. When used with the Sonendo GentleWave™ Molar Handpiece, the System is indicated for 1st and 2nd molar teeth. When used with the Sonendo GentleWave™ Anterior/Premolar Handpiece, the System is indicated for anterior and premolar teeth.

AND/OR

Prescription Use __X___ (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary
K143448

This 510(k) summary information is being submitted in accordance with 21 CFR 807.92

Applicant	Sonendo, Inc.
Date Prepared	April 28, 2015
Contact	Jenny Fam Senior Director, Regulatory Affairs 26061 Merit Circle, Suite 101 Laguna Hills, CA 92653 949-766-3636
Trade Name	Sonendo GentleWave™ System
Common Name	Sonic Cleaning and Irrigation System
Classification	Ultrasonic Scaler
Device Classification	Class II per 21 CFR 872.4850
Product Code	ELC
Predicate Devices	Primary: Sonendo OmniClean Endotherapy System (K133752) Reference: EMS Piezon Master 700 (K093000)

Substantial Equivalence:

The Sonendo GentleWave System is substantially equivalent in intended use, principle of operation and technological characteristics to the Sonendo OmniClean Endotherapy System (K133752) and the EMS Piezon Master 700 (K093000).

Description of the Device Subject to Premarket Notification:

The Sonendo GentleWave System (Console and Handpiece) delivers a stream of degassed treatment fluids into the tooth. The treatment fluids delivered to the tooth include a 3% Sodium Hypochlorite (NaOCl) solution and an 8% Ethylenediaminetetraacetic (EDTA) solution which are commonly utilized in traditional endodontic treatments. The stream of solutions delivered into the tooth come in contact with accumulated fluid and are redirected by a deflection plate, creating hydroacoustic and hydrodynamic effects which result in removal of organic and inorganic debris from the root canals. The Console collects the treatment fluid from the tooth into a waste collection canister.

The GentleWave System requires use with a Sonendo Handpiece: A Molar Handpiece which is used to treat 1st and 2nd molar teeth or the Anterior/Premolar Handpiece which is used to treat anterior and premolar teeth. The Molar and Anterior/Premolar Handpieces are hand held dental instruments which are connected to the Console and provide treatment fluid delivery and waste fluid recovery. The Molar Handpiece is used with various accessories provided with the System. Both the Molar and Anterior/Premolar Handpieces are provided sterile and intended for single use only.

Indications for Use:

The Sonendo GentleWave System is intended to prepare, clean, and irrigate teeth indicated for root canal therapy. When used with the Sonendo GentleWave Molar Handpiece, the System is indicated for 1st and

2nd molar teeth. When used with the Sonendo GentleWave Anterior/Premolar Handpiece, the System is indicated for anterior and premolar teeth.

Technological Characteristics:

The Sonendo GentleWave System has similar physical and technological characteristics to the predicate devices. The differences in physical (weight, dimensions) and electrical (power usage, frequency range) characteristics when compared to the EMS Piezon Master do not affect substantial equivalence.

Characteristics	**Sonendo GentleWave System (K143448)**	**Primary Predicate: Sonendo OmniClean Endotherapy System (K133752)**	**Reference Predicate: EMS Piezon Master 700 (K093000)**
Indication for Use	The Sonendo GentleWave System is intended to prepare, clean and irrigate teeth indicated for root canal therapy. When used with the Molar Handpiece, the System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy. When used with the Anterior/Premolar Handpiece, the System is intended to prepare, clean and irrigate anterior and premolar teeth indicated for root canal therapy.	The Sonendo OmniClean System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy.	Intended for use in the following dental and periodontal applications: • Preparing, cleaning and irrigating root canals • Retrograde preparation of root canals • Removing supra and sub-gingival calculus deposits and stains from teeth • Periodontal pocket lavage with simultaneous ultrasonic tip movement • Scaling and root planning • Releasing crowns, bridges, inlays and posts as well as condensing gutta percha • Plugging for amalgam condensation • Cavity preparation, cementing inlays and onlays
Principle of Operation	Generation of hydroacoustic waves and fluid motion. The tip of the device is placed in or on top of the tooth during cleaning. Hydroacoustics are created by the treatment fluid stream flowing through the enclosure and coming into contact with the fluid inside the tooth at the distal tip. The fluid stream is dispersed and deflected by the deflection plate of the enclosure creating hydrodynamics (fluid motion) within the tooth.	Generation of hydroacoustic waves and fluid motion. The tip of the device is placed in or on top of the tooth during cleaning. Hydroacoustics are created by the water treatment fluid stream flowing through the enclosure and coming into contact with the fluid inside the tooth at the distal tip. The fluid stream is dispersed and deflected by the deflection plate of the enclosure creating hydrodynamics (fluid motion) within the tooth.	Generation of hydroacoustic waves and fluid motion

Characteristics	Sonendo GentleWave System (K143448)	**Primary Predicate:** Sonendo OmniClean Endotherapy System (K133752)	**Reference Predicate:** EMS Piezon Master 700 (K093000)
Treatment Site	Root canal	Root canal	Various, including Root canal
Components	Console (Control Unit), Irrigation Fluid Reservoirs, Foot Pedal, Handpiece and Accessories	Console (Control Unit), Irrigation Fluid Reservoirs, Foot Pedal, Handpiece and Accessories	Control Unit, Irrigation Fluid Reservoirs, Foot Pedal, Handpiece and Instruments
Irrigation Fluids	3% Sodium Hypochlorite (NaOCl) solution and 8% EDTA solution	3% Sodium Hypochlorite (NaOCl) solution and 8% EDTA solution	Various, including 0.3% Sodium Hypochlorite (NaOCl) solution and low grade acids
Handpiece Type	Two (2) Offered: Molar Handpiece and Anterior/Premolar Handpiece	One (1) Offered: Molar Handpiece	Universal Handpiece with various attachments.
Sterility: Handpiece	Sterile, Single Use Only	Sterile, Single Use Only	User sterilized, Reusable
Sterility: Console	Non-Sterile, User Disinfected, Reusable	Non-Sterile, User Disinfected, Reusable	Non-Sterile, User Disinfected, Reusable
Materials	Medical Grade Materials	Medical Grade Materials	Medical Grade Materials
Flow rate	With Molar Handpiece: 45±10 ml/min With Anterior/Premolar Handpiece: 35±10 ml/min	With Molar Handpiece: 50±10 ml/min	50 ml/min
Maximum Ultrasonic Output	21 watts	21 watts	12 watts
Frequency range	With Molar Handpiece: 0.5-14 kHz With Anterior/Premolar Handpiece: 0.5-32 kHz	Molar Handpiece: 0.5-14 kHz	24-32 kHz
Supply voltage	100-240V, 50-60Hz	100-120V, 50-60Hz 120-240V, 50-60Hz	100-240 VAC/ 50-60 Hz
Power usage	6 VA	6 VA	80 VA
EN 60601-1 classification	Class I Applied Part, Type B, IP 20, unit	Class I Applied Part, Type B, IP 20, unit	Class I Applied Part, Type BF, IP 20, unit
Weight	60 kg	59 kg	2.4 kg
Unit Dimensions (mm)	305 x 584 x 1066	305 x 584 x 1066	225 x 280 x 295
Operating conditions	10°-40°C, 30-75% Rh	10°-40°C, 30-75% Rh	10°-40°C, 30-75% Rh

The differences do not impact substantial equivalence as the differences in the indications and technical specifications are within the range of the identified predicates.

Performance Data:

All necessary performance testing has been conducted on the Sonendo GentleWave System to assure substantial equivalence to the predicate devices and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. The device passed the following tests, which were conducted in accordance with noted standards:

Test	Consensus Standard/FDA Guidance/Description
Sterility	Sterile per ISO 11137-1,-2*, Sterilization of health care products – Radiation Sterilization*
Biocompatibility	Biocompatible per ISO 10993-1, -5, -10, -11, *Biological Evaluation of Medical Devices*
Electromagnetic Compliance and Electrical Safety	Certified per IEC 60601-1 *General Requirements for Basic Safety and Essential Performance* and IEC 60601-1-2 *Medical Electrical Equipment*: *Safety, Radiofrequency Emissions and Electromagnetic Immunity*.
Software	Validated per FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,* 2005.
Thermal Test	Internal Test Method: Determined the temperature generated on the external surface of the tooth when receiving treatment with the device.
Cavitation Test	Internal Test Method: Evaluated transient cavitation bubbles which clean root canals.
Hydroacoustics Test	Internal Test Method: Demonstrated hydroacoustic characteristics of the device.
Cleaning Test	Internal Test Method: Demonstrated cleaning efficacy of the device on extracted teeth.
Apical Pressure Test	Internal Test Method: Determined the hydraulic pressure exerted at the apical terminus of the root canal during use of the device.
Apical Extrusion Test	Internal Test Method: Measured the relative volume of treatment fluid extruded through the apical terminus during use of the device.

Basis for Determination of Substantial Equivalence:

Upon reviewing the information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the Sonendo GentleWave System is substantially equivalent to existing legally marketed devices.